

IN THE CLAIMS

The claims are reproduced below for the Examiner's convenience.

Claim 1 (Previously Presented): A pharmaceutical formulation comprising

- a) an inner layer with the active ingredient budesonide bound in a binder
- b) an intermediate layer with a polymeric coating agent which is soluble in intestinal juice or extends release,
- c) an outer envelope which is resistant to gastric juice or an outer layer with a coating agent which is resistant to gastric juice

where the layers may comprise further pharmaceutically acceptable excipients,

wherein the binder is a polymer or copolymer with acidic groups, and the formulation of the inner layer without intermediate and outer layer releases the bound active ingredient in the release test according to USP XXIII monograph <711> "Dissolution" with apparatus 2 (paddle) with 100 revolutions/min in phosphate buffer of pH 7.5 to the extent of more than 80% after 30 min.

Claim 2 (Previously Presented): The pharmaceutical formulation as claimed in claim 1, wherein the polymeric binder is a (meth)acrylate copolymer which comprises 40 to 95% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 5 to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical.

Claim 3 (Previously Presented): The pharmaceutical formulation as claimed in claim 1, wherein the polymeric binder is a vinylpyrrolidone/vinyl acetate copolymer.

Claim 4 (Previously Presented): The pharmaceutical formulation as claimed in claim 1, wherein the intermediate layer is a (meth)acrylate copolymer which comprises 40 to 100% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and no or up to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical.

Claim 5 (Previously Presented): The pharmaceutical formulation as claimed in claim 1, wherein the intermediate layer is a (meth)acrylate copolymer which comprises 85 to 98% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 15 to 2% by weight (meth)acrylate monomers with a quaternary ammonium group in the alkyl radical.

Claim 6 (Previously Presented): The pharmaceutical formulation as claimed in claim 1, wherein the outer coating agent which is resistant to gastric juice is a (meth)acrylate copolymer which comprises 40 to 100% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 5 up to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical.

Claim 7 (Previously Presented): The pharmaceutical formulation as claimed in claim 1, wherein the outer envelope which is resistant to gastric juice is a capsule.

Claim 8 (Previously Presented): The pharmaceutical formulation as claimed in claim 7, wherein the capsule consists essentially of gelatin or of hydroxypropylcellulose.

Claim 9 (Cancelled).

Claim 10 (Previously Presented): The pharmaceutical formulation as claimed in claim 6, wherein the pharmaceutical formulation comprises the active ingredient in the form of pellets or granules.

Claim 11 (Previously Presented): The pharmaceutical formulation as claimed in claim 1, wherein the pharmaceutical formulation is a multiparticulate pharmaceutical form with substantially uniform release of budesonide in the small intestine and in the large intestine, which comprises at least two different types of pellets, one type of pellet releasing the active ingredient predominantly in the pH range of the small intestine and the other predominantly in the pH range of the large intestine.

Claim 12 (Previously Presented): The pharmaceutical formulation as claimed in claim 11, wherein the pellets are enclosed in a capsule comprising (meth)acrylate copolymer which comprises 40 to 100% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 5 up to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical.

Claims 13-16 (Cancelled).

Claim 17 (Withdrawn): A pharmaceutical formulation comprising

- a) an inner layer with the active ingredient budesonide bound in a binder which is a (meth)acrylate copolymer which comprises 40 to 95% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic

acid and 5 to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical

- b) an intermediate layer with a polymeric coating agent which is a (meth)acrylate copolymer which comprises 85 to 98% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 15 to 2% by weight (meth)acrylate monomers with a quaternary ammonium group in the alkyl radical and that is soluble in intestinal juice or extends release,
- c) an outer envelope which is a (meth)acrylate copolymer which comprises 40 to 100% by weight free-radical polymerized units of C₁- to C₄-alkyl esters of acrylic or methacrylic acid and 5 up to 60% by weight (meth)acrylate monomers with an anionic group in the alkyl radical and that is resistant to gastric juice or an outer layer with a coating agent which is resistant to gastric juice

where the layers may comprise further pharmaceutically acceptable excipients,

wherein the binder is a polymer or copolymer with acidic groups, and the formulation of the inner layer without intermediate and outer layer releases the bound active ingredient in the release test according to USP XXIII monograph <711> "Dissolution" with apparatus 2 (paddle) with 100 revolutions/min in phosphate buffer of pH 7.5 to the extent of more than 80% after 30 min.